

REMARKS

The Office Action mailed January 27, 2006, has been received and reviewed. Claims 1-7, 11-16, 20 and 21 are currently pending in the application. Claims 1-7, 11-13, 15, 16, 20 and 21 stand rejected. Claim 14 is objected to. Claims 1, 20 and 21 are amended herein. Amendments have been made without prejudice or disclaimer. No new matter has been added. Reconsideration of the application is respectfully requested.

Examiner interview

Applicant kindly thanks the Examiner for the interview granted on February 21, 2006. The interview summary indicates that Rodney P. Swartz, Ph.D., Allen C. Turner, Johan Renes and Paulos Steverink participated in the interview. The substance of the interview was that applicants' representatives and examiner discussed the meaning of functional equivalent of guanidine thiocyanate and applicants proposed amending the claims to read "chaotropic" agents instead of "functional equivalent." The interview summary indicates that the proposed amendments appear to place the claims in condition for allowance. If further comments regarding the interview are considered helpful or necessary, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Claim rejections—35 U.S.C. § 102(b)

Claims 1-5, 11-13, 15 and 21 are rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Grathwohl *et al.* (*Journal of Virological Methods*, 64:205-216, 1997). Applicants respectfully traverse this rejection because Grathwohl does not teach each and every element of claims 1-5, 11-13, 15 and 21.

The Office asserts that the open language of the instant claims encompasses not only the listed steps, but may also comprise unlisted steps. However, it is respectfully submitted that, open language in the claims does not excuse the cited prior art from teaching each and every element of the instant claims.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053

(Fed. Cir. 1987). Likewise, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Amended independent claims 1 and 21 recite, in part, obtaining a sample from a mammal and using that sample to prepare a *test set and a control set* that are then assayed for the presence of prion protein. Treatment with guanidine thiocyanate (GdnSCN) or one or more chaotropic agents is then used to denature proteins in the test set, while the control set is left untreated. The use of objective controls acts as an internal check on the validity of the test, and results in a reduced risk of scoring a false positive test result.

Applicants respectfully affirm that Grathwohl does not disclose the use of a *control set along with a test set* including GdnSCN or one or more chaotropic agents used to denature proteins in the test set, while the control set is left untreated. Grathwohl teaches that all tissue samples are treated with initial mincing with scissors and then digested with collagenase, DNase I and proteinase K, all in the presence of non-ionic detergents. Grathwohl, col. 2, p. 206 and col. 1, p. 201. Also, Grathwohl teaches that, after boiling in 5% SDS, tissue extracts are dissolved in different concentrations of GdnSCN in PBS in order to increase adsorption of PrP^{Sc} to microtiter plates. *Id.* at cols. 1-2, page 208. However, Grathwohl does not teach using at least one tissue sample to prepare a test set and a control set, the test set treated with GdnSCN or one or more chaotropic agents, while the control set is left untreated.

As discussed in the interview, applicants affirm that the manner and use of GdnSCN is unique as recited in amended independent claims 1 and 21.

More particularly, in Grathwohl, a buffer containing GdnSCN is used to resolublize a mix of proteins after precipitation in methanol prior to adsorption onto microtiter plates for ELISA analysis. In contrast, amended independent claims 1 and 21 disclose the use of GdnSCN or one or more chaotropic agents in a PrP-specific fashion after the protein has been immobilized to a solid phase to create a differential in antibody reactivity between treated and untreated samples. If GdnSCN were used in the instant case as taught by Grathwohl, then the effect that is disclosed in claims 1 and 21 that allow one to readily differentiate between PrP^{Sc} and PrP^C containing samples would be lost.

Therefore, Grathwohl does not disclose each and every element of amended independent claims 1 and 21, or those claims dependent therefrom. As such, withdrawal of the rejection of

claims 1-5, 11-13, 15 and 21 under 35 U.S.C. § 102(b) is requested.

Claim rejections—35 U.S.C. § 103(a)

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Grathwohl. Applicants respectfully traverse this rejection for the following reasons.

To establish and maintain a *prima facie* case of obviousness under 35 U.S.C. § 103, M.P.E.P. § 706.02(j) states that the prior art reference must teach or suggest all the claim limitations.

Dependent claims 6 and 7 are nonobvious under Grathwohl *et al.* because, *inter alia*, amended independent claim 1 is nonobvious because Grathwohl does not teach or suggest each and every element of independent claim 1. "If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious." MPEP § 2143.03.

Reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejections under Grathwohl *et al.* are respectfully requested.

Claim Rejections—35 U.S.C. § 112, second paragraph

Claims 14 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention.

With regard to claim 14, it is respectfully submitted, for those reasons discussed *supra*, that claim 14 depends from allowable claim 13 and, therefore, is not indefinite.

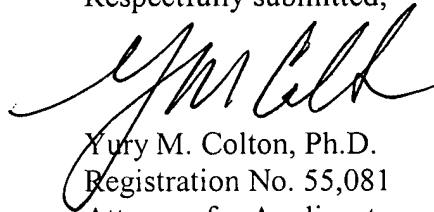
Applicants amended claim 20 as discussed in the interview and, thus, any grounds for rejection should be removed.

Reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph, rejections are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, the applicants submit that the claims define patentable subject matter and a notice of allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Yuri M. Colton', is written over the typed name and address.

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